

REMARKS

1. Applicant will be retaining claims 1-40 in the application and will be filing claims 41-59 in a divisional application. Applicant has added claims 60-78 in this amendment.

Applicant has amended the claims to overcome the objections of the Examiner. Applicant has also amended the claims to correct informalities noted by applicant's attorney upon a further study of the claims. As now written, the claims are believed to be definite.

2. For many generations, doctors have been monitoring the hearts of patients to determine if the patients have any heart problems or other problems resulting from deficiencies in the characteristics of the patient's heart beats. However, the monitoring of the patient's heart beat has been only partially effective. Noise in the heart signals has prevented the monitored heart signals from accurately determining problems in the patient's heart. The deviations in the monitored heart signals have resulted from noise in the signals. This noise has resulted, for example, from movements of the patient while the heart signals of the patient are being monitored. The deviations in the characteristics of the patient's heart signals resulting from noise have been known for generations. Concerted efforts have been made for generations to eliminate noise in the signals but with out any major success. The problems of heart signals recorded with inaccurate characteristics have persisted through successive generations to the present.

3. Applicant provides a system which monitors a patient's heart signals at an electrode attached to the patient. The system eliminates noise from the heart signals at the electrode and provides output signals with characteristics corresponding only to the heart signals at the electrode. Since applicant's system produces signals with characteristics corresponding to the signals provided by the electrode attached to the patient, applicant's system indicates heart deficiencies and other deficiencies not recognized in the prior art. The advantages of applicant's system have been recognized

by the Cleveland Clinic and Duke Clinical Research Institute. The Cleveland Clinic and Duke Institute are recognized as two of the finest heart centers in the United States.

4. Claims 35 and 36 have been rejected under 35 U.S.C. 102(b) as being anticipated by Blancke, U.S. Patent No. 4,243,044. As now written, claims 35 and 36 are allowable over Blancke for certain important reasons.

As now written claim 35 recites an amplifier adapted to be connected to the electrode and constructed to pass the signals from the electrode through the amplifier without losing signal strength and without any changes in signal characteristics of the signals at the electrode.

Applicant's system provides a single ground. The single ground is the true patient ground. Applicant's system does not additionally provide a floating ground. This operational amplification of applicant's system accordingly provides output signals with characteristics corresponding to the characteristics of the signals at the electrodes.

Blancke does not provide an amplifier constructed to pass the signal from the electrode through the amplifier without loss in signal strength and without changes in signal characteristics from the characteristics of the signals at the electrodes. This may be seen from the fact that this is not what Blancke is attempting to accomplish or has accomplished in his patent.

Blancke provides a system with a true ground and a floating ground. Blancke's system provides and maintains a relationship between the true ground and the floating ground. This is one of the primary features of Blancke's system. As will be seen from Figure 1 in Blancke's patent, Blancke provides a plurality of diverse and unrelated circuits for maintaining this relationship between true ground and floating ground. These additional circuits prevent the output signals from the amplifiers in Blancke from having the identical characteristics of the signals from the electrodes. They also prevent the output signals from the amplifier from having the identical strength of the signals on the electrodes.

The intent of Blancke is to use a unity gain amplifier to drive a floating ground toward a common mode potential on a patient's body. To accomplish this, Blancke provides the circuitry of Figure 1. This circuitry is partially located between the electrode and the amplifier so Blancke cannot provide an output signal from an amplifier without any change in the characteristics of the signal from the electrode.

Claim 36 is dependent from Claim 35 and is accordingly allowable over Blancke for the same reasons as Claim 35. Claim 36 is also allowable over Blancke because Blancke does not disclose a circuit constituting a low pass filter connected differentially to the electrode to eliminate noise in the signals from the electrode and the environment.

5. Claims 1, 2, 13-15, 18, 19, 21, 22, 24, 25, 27, 28, 30-32 and 38-40 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Traub et al., U.S. Patent No. 5,427,111 and in view of Gober, U.S. Patent No. 5,052,398. As now written, these claims are allowable over Traub in view of Gober for certain important reasons.

Applicant provides a voltage on electrodes adapted to provide a true ground on a patient's body. Applicant does not provide a different ground voltage (e.g., a floating ground) from a patient's body on a monitor.

Traub provides for ground voltages from a patient's body on electrodes adapted to be connected to the patient's body. Traub also provides for different ground voltages on a monitor. Traub attempts to provide adjustments between the ground voltages on the electrodes and the ground voltages on the monitor by injecting corresponding current into the electrodes. Since applicant deals only with the ground voltages on the electrodes and not with the ground voltages on the monitor and does not inject a current into the electrode and therefore into the patient, applicant's system is simpler and safer and more accurate than Traub's system. Furthermore, Traub discloses that a combination of the resistors 28 and 29 and the capacitors 30 and 31 is provided between the electrodes 25 and 26 and the current sources 41 and 42 and the amplifiers 32 and 33. This changes the voltages on the electrodes 25 and 26 and provides voltage differences between the

electrodes. The differences between applicant and Traub as specified in this paragraph are fundamental. They prevent Traub from providing signals without loss in signal strength and with characteristics corresponding to the characteristics of the signals on the electrodes.

Traub provides an arrangement including resistors 36 and 37 and start point 38. The start point 38 generates a voltage which is an average across the amplifiers 32 and 33.

The start point voltage 38 generates a voltage in an amplifier 39. The amplifier 39 is not a differential amplifier. The amplifier voltage 39 provides at a feedback line 40 a voltage which controls the operation of current sources 41 and 42. The voltages on the current sources 41 and 42 control the relative ground voltages on the electrodes and on the monitor. This causes the output of the amplifiers 32 and 33 to have different signal characteristics than the signals on the electrodes 25 and 26.

Traub has another significant disadvantage which prevents it from being a good prior art reference against applicant's claims. Traub provides a first single-ended low pass filter defined by the electrode 25, the resistor 28 and the capacitor 30. Traub also provides a second single-ended low pass filter defined by the electrode 26, the resistor 29 and the capacitor 31. This shows that Traub knew about low pass filters. However, Traub provides an output from amplifiers 32 and 33 including the resistors 36 and 37 and the start point 38 and also provides a feedback to the amplifiers 32 and 33 including the feedback line 40 and the current sources 41 and 42. This prevents the amplifiers 32 and 33 in Traub from having a signal identical to the signal at electrode 25 and 26.

Gober also does not disclose a system as recited in applicant's claims. Gober discloses a low pass filter 42, a high pass filter 44 and an absolute value function filter 46. Therefore, the output of the Gober system is not a true signal from electrodes. Furthermore, there is nothing in Gober to indicate that the low pass filter 42 in Gober is chosen rather than the filters 4 and 46. There is also nothing in Gober to indicate the

filter 42 is connected, or should be connected, in a differential relationship or that they should be differentially connected with electrodes and a single ground.

According to the Examiner, Gober discloses low pass filters which eliminate noise. Furthermore, according to the Examiner, it would have been obvious to include the low pass filter of Gober in the system of Traub.

The Traub patent issued in 1995. The Gober patent issued in 1991. Since Gober issued before Traub, it was available to Traub or a third party to combine Gober with Traub and allegedly obtain applicant's invention. Traub failed to do this. So did everyone else throughout the world until applicant's invention. Furthermore, Traub disclosed a low pass differential filter but did not connect the low pass filter to an operational amplifier. This indicates that the combination of Traub and Gober was not obvious to persons of ordinary skill in the art or even persons with the greatest of skill in the art. Furthermore, since Gober issued in 1991, it has been a period of eleven (11) years where the combination of Traub and Gober was available to provide applicant's invention. This is more than a lifetime in a field as active as heart monitoring systems. No one even suggested this combination in the Traub patent.

Applicant's system is just being introduced to the market. It has received widespread acceptance in a short period of time. Applicant's system eliminates noise so that it monitors the heart beats actually produced in a patient. This is different than the other systems now on the market. Those systems monitor heart beats with a significant amount of noise. This noise prevents the prior art systems from determining and monitoring the actual heart beats of the patient. As a result, applicant's system detects abnormalities in a patient's heart beats that the other systems have not been able to do.

There are other reasons why applicant's claims are allowable over the combination of Traub and Gober. In applicant's system, the electrodes 12 and 14 are adapted to connect directly to the input terminals of the amplifiers 16 and 18. This allows the input signals to the amplifiers 16 and 18 to have the same strength and the same characteristics

as the signals on the electrodes 12 and 14, particularly since the amplifiers have input impedance approaching infinity. However, in Traub, energy is lost in the passage of the signals from the electrodes 25 and 26 through the resistors 28 and 29 and the line 40 to the input terminals of the amplifiers 32 and 33. Energy is also lost in Traub in the passage of signals from the start point 30 to the current sources 41 and 42 and from the output of the amplifiers 32 and 33 through the resistors 36 and 37 to the start point 38. The resistors 36 and 37 and the current sources 41 and 42 and the relationship between the resistors 28 and 29, the capacitors 30 and 31 and the resistors 36 and 37 also prevent the output signals from the amplifiers 32 and 33 in Traub from having the identical characteristics of the signals from the electrodes 25 and 26.

The low pass filters in applicant's system are in a differential relationship. There are no low pass filters at the output of the electrodes 25 and 26 in Traub, even though Traub knew about low pass filters. There are low pass filters in Gober but they are not in a differential relationship and they are not connected to operational amplifiers.

In view of the above, claims 1, 2, 13-15, 18, 19, 21, 22, 24, 25, 27, 30-32 and 38-40 are allowable over the combination of Traub and Gober because of the following recitations in the claims:

Claim 1

An amplifier having an input terminal with an impedance approaching infinity and providing at an output terminal signals having characteristics corresponding to the characteristics of the signals from the electrodes to eliminate noise resulting from movement of the patient.

An output stage connected to the amplifier and constructed to reject remaining noise and constituting a differential low pass filter to pass signals at frequencies below a particular value.

Claim 2

A second amplifier corresponding to the first amplifier and adapted to be connected to the second electrode.

A common mode rejection provided in the low pass filter and amplifiers to the signals from the electrodes to eliminate noise from the signals provided by the electrodes.

Claim 13

A pair of amplifiers respectively adapted to be connected to the first and second electrodes and having properties of providing a high input impedance approaching infinity and having a low output impedance to eliminate noise resulting from movements of the patient.

A pair of low pass filters differentially connected to the amplifiers for eliminating noise and for passing signals at relatively low frequencies with characteristics identical to the characteristics of the signals on the electrodes.

Claim 14

The amplifiers are connected on a differential basis to obtain the difference between the signals on the first and second electrodes and are provided with substantially identical constructions.

Claim 15

The amplifiers provide a differential relationship for eliminating noise resulting from movements of the patient without affecting the strength of the signals and without affecting the characteristics of the signals from the electrodes.

Claim 21

The first and second amplifiers are adapted to be connected in a differential relationship to the first and second electrodes to eliminate noise even during movements

of the patient and to produce an output signal representing the difference between the signals on the electrodes.

Claim 18

Dependent from allowable claim 13.

Claim 19

The amplifiers are adapted to obtain the difference between the signals on the first and second electrodes.

The amplifiers provide a differential relationship to eliminate noise resulting from movements of the patient.

Dependent from allowable claim 13.

Claim 22

The first and second amplifiers have substantially identical characteristics in a differential relationship to provide output signals having characteristics corresponding to the characteristics of the signals on the first and second electrodes.

Dependent from allowable claim 21.

Claim 24

Each of the first and second amplifiers has a low output impedance with substantially identical characteristics

Dependent from allowable claim 22.

Claim 25

A pair of low pass filters are differentially connected to the first and second electrodes for producing low frequency signals representing the difference between the signals on the electrodes.

A pair of substantially identical amplifiers are differentially connected to the pair of low pass filters to eliminate noise produced in the electrodes from movements of the patient.

Each of the amplifiers has an input impedance approaching infinity and substantially identical constructions to produce signals having characteristics corresponding to the characteristics of the signals on the electrodes.

Claims 27, 30 and 32

Respectively dependent from allowable claim 25.

Also, in claim 32, the amplifiers include a pair of transistors having terminals respectively adapted to be connected to the first and second electrodes.

Claim 38

A pair of amplifiers, each adapted to be connected to an individual one of the electrodes to pass signals from an individual one of the electrodes and to provide output signals having characteristics corresponding to the difference between the characteristics of the signals on the electrodes without loss in the strength of the signals on the electrodes and without changes in the characteristics of the differences of the signals on the electrodes, the amplifiers being provided with characteristics, and being differentially connected to each other, to eliminate noise resulting from movements of the patient during the production of the signals on the electrodes.

Claim 31

The low pass filters include a plurality of capacitors differentially connected to the pair of amplifiers.

Dependent from allowable claim 25.

Claim 40

The differential circuitry operates as low pass filters to further eliminate noise and the electrodes have identical characteristics and the amplifiers have identical characteristics.

Dependent from allowable claim 39.

The low pass filters in Gober are not connected in a differential relationship. Gober does not state that the amplifiers have identical characteristics.

6. Claims 3, 5, 11, 17, 20, 23 and 26 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Traub and Gober as applied to claims 1, 2, 13, 21 and 25 and further in view of Callahan patent No. 4,424,816.

Claims 3, 5, 16, 17, 20, 21 and 25 are allowable over the prior art because they are dependent from allowable claims.

7. Claims 6-12 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Hannula patent application publication 2002/0021813 and in view of Traub.

Applicant respectfully submits that the Examiner has misinterpreted Hannula and Traub in rejecting claims 6-12.

This may be seen from the following:

a. Paragraph 0031 in Hannula does not disclose an amplifier connected to an electrode to amplify the signal at the electrode without producing noise resulting from movements of the patient.

b. Paragraphs 31 and 76 in Hannula do not disclose a low pass filter connected to the amplifier to provide an input in which remaining noise is eliminated and signals in a particular frequency range are passed by the low pass filter.

c. Traub does not disclose an amplifier having a low output impedance. (See Traub, column 4, lines 24-28), to provide optimum parameter sensing capabilities of a device. This may be seen from the discussion above where applicant indicates that Traub has not removed the noise from the amplifier.

In view of the above the combination of Hannula and Traub does not provide a disclosure having the following recitals in claim 6:

1. An amplifier adapted to be connected to the electrodes to amplify the signals on the electrodes without producing noise resulting from movements of the patient and without changing the characteristics of the signals (from the amplifier) from the signal on the electrode.

2. A low pass filter connected to the amplifier to provide an output in which remaining noise is eliminated and signals in a particular frequency range are passed by the low pass filter.

Hannula and Traub also do not disclose the recital in claim 7 that the amplifier constitutes a differential amplifier for eliminating noise from the signals provided by the electrodes.

Hannula also does not disclose the recitals in claim 8 that the amplifier constitutes a differential amplifier for eliminating noise from the signals provided by the electrodes.

Claims 9 and 10 are allowable over the commitment of Hannula and Traub because they are dependent from allowable claim 6.

Claim 11 recites that the low pass filter limits the amplitudes of the output from the amplifier to facilitate the operation of the amplifier in processing the signals. Hannula and Traub do not disclose this.

Claim 12 is allowable over the combination of Hannula and Traub for the same reasons as claim 11.

Claims 7-12 also are allowable over the combination of Hannula and Traub because they are dependent from allowable claims.

8. Claim 29 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Traub and Gober as applied to claim 26 above, and further in view of Yonce, U.S. Patent Application publication 2001/0021813.

Applicant has indicated in the discussion above relating to Traub and Gober a number of reasons why Traub and Gober do not apply to applicant's invention as recited in claims 1, 2 and 25.

Claim 29 is dependent from claim 25 and is allowable over the combination of Traub and Gober for the same reason as claim 25. Specifically, Traub and Gober do not disclose the low pass filter and the amplifier recited in claim 25. Claim 29 recites the embodiment shown in Figure 6 where first differentially connected low pass filters are provided at inputs to the amplifiers and second differentially connected low pass filters are provided at the output of the amplifier. Traub, Gober and Yonce do not disclose this.

9. Claims 33 and 34 have been rejected under 15 U.S.C. 103(a) as being unpatentable over Hannula and Traub as applied to claim 6 and further in view of Yonce.

Claim 33 is dependent from allowable claim 6. Claim 33 is also allowable over the cited references because of the recitation of the characteristics of the amplifiers and the low pass filters connected to the amplifiers. Claim 33 is further allowable over the combination of Hannula, Traub and Yonce because none of these references discloses (a) a first low pass filter connected to the output of the amplifier and provided with characteristics to provide an output in which noise is eliminated and signals at a particular frequency are passed by the low pass filters and (b) a second low pass filter is connected

between the electrode and the input of the amplifier and is provided with characteristics to eliminate noise and to pass signals in the particular frequency range.

Claim 34 is allowable over the combination of Hannula, Traub and Yonce for the same reason as claim 33 because it is dependent from allowable claim 33. Claim 34 is also allowable over the combination of references because it recites that the first low pass filter operates on a differential basis and the second low pass filter operates on the differential basis in conjunction with the first low pass filter. None of the references discloses first and second differentially connected low pass filters.

10. Claim 37 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Blancke as applied to claim 36 and in view of Gober. Claim 37 is indirectly dependent from claim 35 which recites that an amplifier is connected to an electrode and is constructed to pass the signal from the electrode through the amplifier without loss in signal strength and without any change in signal characteristics of the signals from the electrode. This is not disclosed in any of the cited references. Claim 37 additionally recites that a circuit is connected to the output of the amplifier to operate as a low pass filter to eliminate noise in the signal in the amplifier. This is also not disclosed in any of the cited references.

11. Applicant has added claims 60-78 by this amendment. Claims 60-69 are allowable over the references for the reasons discussed in detail above. Claims 60-69 are dependent claims. They recite that the low pass filters are formed from a resistor and a capacitor and that the output is provided across the capacitor. Some of claims 60-69 also recite the relationship between the electrode, the amplifier and the resistor and the capacitor in the low pass filter. This relationship is not disclosed in any of the cited references.

Claims 68-78 are also dependent claims and are accordingly allowable over the references for the reasons discussed above. Claims 70-78 recite that the apparatus has a single ground. This is in contrast to Blancke and Traub which disclose a true ground and a floating ground and circuitry forming a controlled relationship between the true ground

and the floating ground.

The Examiner has treated Blancke and Traub as the primary references against the claims. Because of this, the recitation of the single ground in claims 70-78 cause the claims to be allowable over the cited references.

12. In order for different prior art references to be combined to reject a claim, the references have to disclose or suggest the combination recited in the claim. *ACS Hospitality Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 221 USPQ 929 (Fed. Cir. 1984). As the Federal Circuit indicated in the ACS case at 732 F.2d. 1572, 1577, 221 USPQ 929, 933:

“Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention absent some teaching or suggestion supporting the combination. Under Section 103, teaching of references can be combined only if there is some suggestion or incentive to do so.”

See also *In re Fine*, 837 F.2d 1071, 5 USPQ 2d. 1596, (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ 2d. 1941 (Fed. Cir. 1992) in support of the holding in the ACS case.

None of the references (Blancke, Traub and Gober) cited by the Examiner to reject the claims in this application discloses or suggests certain of the features recited in the claims. These features are specified above for each of the claims in the application. This has been discussed above in some detail. The references cannot accordingly be combined to reject the claims.

13. Reconsideration and allowance of this application are respectfully requested.

14. The Commissioner is authorized to charge any deficiencies in fees or credit any overpayments to our Deposit Account No. 06-2425.

Respectfully submitted,

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